

II. REMARKS:

A. Status of the Claims

Claims 1-18 were originally filed with the case. An Office Action requesting that Applicants select a single species for examination was mailed on October 7, 2005. Applicants timely responded, electing the species of AIT-082. Another Restriction Requirement was mailed on January 26, 2006, asserting that the application claimed three patentably distinct inventions and requiring that Applicants elect an invention for examination. Applicants timely responded, electing the Group I invention, directed to a method of treating dry eye. Therefore, claims 1-6 were the subject of the present Office Action. Claims 1-6 are rejected herein. Claims 1, 5, and 6 are amended herein, claim 4 is cancelled herein and claims 7-18 are withdrawn as being directed to a non-elected invention. No claims are added herein. Support to the amendments to claim 1 can be found in the specification and in the claims as originally filed.

B. The Claims are Patentable Over Wallace and WO 00/32197

The Action rejects all claims as being obvious over Wallace and WO 00/32197. Wallace is said to teach the use of neurotrophic factors for the treatment of a number of eye disorders, including dry eye. The Action acknowledges that Wallace lacks a teaching of AIT-082. WO 00/32197 is said to teach that AIT-082 is a well-known neurotrophic factor. Thus, the Action asserts that it would have been obvious for a person skilled in the art to use AIT-082 for the treatment of dry eye. Applicants respectfully traverse.

It is well settled patent law that "obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." *See In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); MPEP § 2143.01. The Action argues that the skilled artisan would have been motivated to combine the teachings of the cited references since one relates to the use of neurotrophic factors in general for the treatment of dry eye and the other relates to the use of AIT-082 as a neurotrophic factor.

Wallace appears to discuss compositions containing a neurotrophic factor and their use in the treatment of ocular disorders associated with ciliary ganglionic nerve cell degeneration. The neurotrophic factors discussed in Wallace are proteinaceous compounds characterized by having a pI in the range of 5.6 to 7.0 and a molecular weight of about 31.5 kD (Wallace, col. 2, lines 39-42). It is difficult to exploit peptide or protein molecules pharmaceutically due to bioavailability problems generally resident in the pharmaceutical administration of peptides (Spec. page 4, lines 11-13). Therefore, the methods of the present invention focus on the use of small molecule compounds that promote neuron regeneration or neurite outgrowth in a pharmaceutically acceptable vehicle to treat dry eye resulting from injury to corneal nerves. Wallace does not suggest the use of any compounds other than the neurotrophic factors themselves. That is, Wallace contains no suggestion to use small molecule compounds that promote neuron regeneration or neurite outgrowth would be useful in the compositions and methods described.

WO 00/32917 appears to discuss the use of neurotrophic factor stimulators to treat glaucomatous neuropathy and other retinal and optic nerve head degenerative diseases. Retinal and optic nerve head degenerative diseases are disorders occurring in the back of the eye. Dry eye resulting from injury to the cornea, however, is a disorder that occurs near the front of the eye. WO 00/32917 does not suggest that the compounds described therein can be used to treat disorders affecting the front of the eye, such as dry eye resulting from injury to the cornea. Therefore, there is no motivation found within either Wallace or WO 00/32917 to combine their teachings to arrive at the claimed invention.

In light of the foregoing arguments, Applicants respectfully request that the obviousness rejection based upon Wallace and WO 00/32917 be withdrawn.

C. Conclusion

This is submitted to be a complete response to the outstanding Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

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Respectfully submitted,

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